



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) **EP 0 609 056 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
15.12.1999 Bulletin 1999/50

(51) Int. Cl.<sup>6</sup>: **A23K 1/16, A23K 1/18,  
A61K 35/74, A61K 31/20,  
A61K 31/41**

(21) Application number: **94300551.2**

(22) Date of filing: **26.01.1994**

(54) **Prescription diet composition for pet animals**

Diätverschreibung für Haustiere

Régime alimentaire prescrit pour animaux familiers

(84) Designated Contracting States:  
**DE FR GB NL**

(30) Priority: **27.01.1993 JP 1198493**

(43) Date of publication of application:  
**03.08.1994 Bulletin 1994/31**

(73) Proprietor:  
**KYOWA HAKKO KOGYO CO., Ltd.  
Chiyoda-ku, Tokyo 100 (JP)**

(72) Inventors:  
• **Matsuura, Ichiro**  
Tokyo (JP)  
• **Saito, Toshizumi**  
Tokyo (JP)  
• **Shimada, Kenjiro**  
Tsuchiura-shi, Ibaraki-ken (JP)

(74) Representative:  
**Lambert, Hugh Richmond et al**  
**D. YOUNG & CO.,**  
**21 New Fetter Lane**  
**London EC4A 1DA (GB)**

(56) References cited:  
**EP-A- 0 241 097** **FR-A- 2 508 282**  
**GB-A- 1 503 094**

- **RECUEIL DE MEDECINE VETERINAIRE, vol.165, no.6/7, 1989, FR pages 651 - 664 P. NGUYEN ET AL. 'Alimentation et troubles cutanes chez le chien'**
- **DATABASE WPI Week 9248, Derwent Publications Ltd., London, GB; AN 92-393236 & JP-A-4 290 820 (IDEMITSU PETROCHEM CO) 15 October 1992**
- **RECUEIL DE MEDECINE VETERINAIRE, vol.158, no.12, 1982, FR pages 821 - 826 D. FROMAGEOT ET AL. 'Influence de l'alimentation du chien sur sa peau et son pelage'**
- **RECUEIL DE MEDECINE VETERINAIRE, vol.166, no.2, 1990, FR pages 87 - 94 D. FROMAGEOT ET AL. 'Intérêt potentiel de la biotine en dermatologie canine'**
- **Food Composition and Nutrition Tables 1989/1990, 4th revised and completed edition, page 157**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

**EP 0 609 056 B1**

## Description

[0001] The present invention relates to a prescription diet composition having prophylactic and therapeutic effect against dermatosis of pet animals.

[0002] Recently, along with longer life spans of pet animals as a result of improvement in veterinary medicine and the trend toward Europeanization of pet food, as well as the unnatural breeding environment of pet animals without regard to their nature, the incidence of adult diseases and diseases caused by metabolism disorders of pet animals has increased.

[0003] Among from these diseases, dermatosis is outwardly observable. Dermatitis easily becomes chronic, and often requires long-term treatment.

[0004] The treatment of dermatosis usually involves intramuscular or subcutaneous injection, oral administration or external application of antibacterial agents, steroids and the like. However, dermatosis is usually difficult to cure in a short period of time with the drugs alone. Moreover, long-term administration of the drugs often results in occurrence of side effects such as secondary adrenal cortical hypofunction, gastrointestinal disorders such as ulcers and bleeding, nephrotoxicity and worsening of the infection.

[0005] It is known that since deficiency of essential fatty acids and biotin is the main cause of canine dermatosis, incorporation of such ingredients into pet foods is effective against canine dermatosis [Fromageot, D. et al., Rec. Med. Vet. 158, (12), 821-826, 1982]. Also, in cats a severe deficiency of  $\Delta$ -6-desaturase inhibits the conversion of linoleic acid into  $\gamma$ -linolenic acid, and incorporation of  $\gamma$ -linolenic acid into pet foods is known (Japanese Published Unexamined Patent Application No. 149054/86). Furthermore, the activity of  $\Delta$ -6-desaturase in dogs is clearly attenuated by aging and diseases such as hepatic diseases and diabetes (Wolter, R.R., Wolter's Canine and Feline Nutrition Science, p.71, published by Nihon Rinsho Co., 1991), and thus the incorporation of poly-unsaturated fatty acids such as dihomo  $\gamma$ -linolenic acid, arachidonic acid, eicosapentaenoic acid,  $\gamma$ -linolenic acid and the like into canine and feline pet foods is known (Japanese Published Unexamined Patent Application No. 215245/89). Nevertheless, the effect of such pet foods is not therapeutic treatment of canine and feline dermatosis.

[0006] The use of antifatulents for the purpose of prevention and treatment of diarrhea and loose passage is known (Japanese Published Unexamined Patent Application No. 118827/76, etc.), but their use for the purpose of prophylactic or therapeutic treatment of pet dermatosis is not known.

[0007] EP-A-0 421 097 discloses a liquid food product on dairy basis for cats which comprises (see example 5, page 9): i) 0.025% by weight of a lactic acid bacteria; and ii) 2% by weight of corn oil, used as a source of polyunsaturated fatty acids, in order to prevent skin diseases in cats (page 2, lines 26-31)

[0008] Recueil de médecine vétérinaire, vol. 166, n°2, 1990, FR, pages 87-97 discloses the problem of biotin deficiencies on the canine tegument (page 91, table IV) and reports on the therapeutic effects of biotin in pet food to treat said deficiencies (page 92, column 2, paragraph 3 - page 93, column 1, paragraph 3).

[0009] Recueil de médecine vétérinaire, vol. 165, n°6/7, 1989, FR, pages 651-664 discloses the problems caused by polyunsaturated fatty acid and biotin deficiencies in animals (pages 654-655) and reports on therapeutic effects achieved by treating the resulting dermatosis by using polyunsaturated fatty acid, such as  $\gamma$ -linolenic acid,  $\alpha$ -linolenic acid, eicosapentaenoic acid, docosahexaenoic acid (pages 659-662).

## Summary of the Invention

[0010] An object of the invention is to provide a prescription diet composition for pet animals, which comprises an anti-flatulent; a poly-unsaturated fatty acid selected from  $\gamma$ -linolenic acid,  $\alpha$ -linolenic acid, eicosapentaenoic acid and docosahexaenoic acid (hereinafter referred to as DHA); and biotin. Another object of the present invention is to provide a method for prophylactic or therapeutic treatment of dermatosis in a pet animal which comprises having the pet animal ingest the prescription diet composition.

## Detailed Description of the Invention

[0011] The  $\gamma$ -linolenic acid,  $\alpha$ -linolenic acid, eicosapentaenoic acid and DHA, etc. may be originated from any source. Specifically, the  $\gamma$ -linolenic acid may be derived from evening primrose oil, a microorganism belonging to the genus *Mortierella* or *Mucor*, an algae belonging to the genus *Euglena* or *Chlorella*, or from extracts thereof. The  $\alpha$ -linolenic acid may be derived from seeds of plants such as *Perilla ocimoides* var. *Perilla crispa ocimoides* L., Linseed, rape seeds, soybean, etc. or from extracted oils thereof. The eicosapentaenoic acid and DHA may be derived from the oils of fishes such as sardines, bonito and tuna, from a microorganism belonging to the genus *Mortierella*, etc. or from extracted fluids thereof. The polyunsaturated fatty acid to be contained in the prescription diet composition of the present invention may be in a free form or in the form of a salt or ester. The salt may be a non-toxic metal salt, for example, sodium salt, potassium salt and calcium salt, and the ester includes, for example, methyl ester, ethyl ester or the like.

[0012] The biotin, or vitamin H, to be contained in the prescription diet composition of the present invention may be either synthesized or extracted from a yeast, a microorganism belonging to the genus Bacillus, Escherichia or Corynebacterium, a plant, an animal organ, or a Chinese medicinal herb such as jumi-haidokuto, shofusan and toki-inshi.

[0013] The antifatulent to be contained in the prescription diet composition of the present invention comprises materials having an action of suppressing the growth of harmful intestinal bacteria and/or of accelerating the growth of beneficial intestinal bacteria. For example, cells of a bacterium selected from lactic acid bacteria such as Lactobacillus acidophilus, Streptococcus faecalis, Lactobacillus bulgaricus, Lactobacillus casei, etc.; bifid bacteria such as Bifidobacterium bifidum, Bifidobacterium longum, Bifidobacterium breve, Bifidobacterium adolescentis, Bifidobacterium pseudolongum, Bifidobacterium thermophilum, etc.; butyric acid bacteria such as Clostridium butyricum, etc.; bacillus such as Bacillus natto, Bacillus toyoi, and the like, as well as treated cells of the bacterium are mentioned. The treated cells include, for example, washed cells, dry cells, freeze-dried cells, freeze-dried cells, acetone-dried cells, organic solvent-treated cells, surfactant-treated cells, lysozyme-treated cells, ultrasonically treated cells, mechanically disrupted cells, or the like.

[0014] The pet animals which may ingest the prescription diet composition of the present invention include small domestic animals such as dogs and cats.

[0015] The concentration of the poly-unsaturated fatty acid in the prescription diet composition of the present invention is 0.5 - 50 wt%, preferably 1 - 25 wt%. The concentration of the biotin is 0.01 - 1.0 wt%, preferably 0.04 - 0.4 wt%. The concentration of the antifatulent is  $10^6$  -  $10^{10}$  cells/per gram of the prescription diet composition (0.00001 to 10 wt% when calculated as dry cell weight).

[0016] In addition to the above-mentioned active ingredients, auxiliary agents may be contained in the prescription diet composition. In order to enhance the effect of the antifatulent, oligosaccharides such as fructooligosaccharide, soybean oligosaccharide, xylooligosaccharide, inulooligosaccharide and lactulose may be added. Also, amino acids such as methionine and taurine; vitamins such as vitamin A, vitamin B<sub>2</sub>, vitamin B<sub>6</sub> and nicotinic acid; and zinc, which are known to be effective in treating dermatosis, may be added. Furthermore, for a nutritional standpoint, yeast extract, dry milk, proteins, enzymes, inorganic substances such as calcium, magnesium and phosphorus, nucleic acids, essential fatty acids such as linoleic acid may be added. For good taste, salts such as sodium chloride, organic acids and sweeteners such as sugar may be added; for the purpose of formulation of the prescription diet composition, emulsifiers such as enzymolytic lecithin, excipients such as lactose, cyclodextrin, grain starch and calcium carbonate may be added; and for stability during transportation and storage, antioxidants such as vitamin E,  $\beta$ -carotene, vitamin C and lecithin may be added.

[0017] The concentration of these auxiliary ingredients in the prescription diet composition of the present invention is 0 - 99.99 wt%, preferably 5 - 95 wt%.

[0018] The prescription diet composition of the present invention may be used in combination with dermatotherapeutic medicines such as antibacterial agents (e.g. lincomycin), antipruritic agents (e.g. prednisolone), analgesics (e.g. salicylic acid), antiinflammatory agents (e.g. prednisolone), antiallergic agents (e.g. hydramine) and adrenal cortical hormone preparations (e.g. prednisolone), for the purpose of heightening the therapeutic effects of these medicines.

[0019] The prescription diet composition of the present invention may be ingested by a pet animal in the form of a powder, granules, pellets, tablets, a paste, an aqueous solution, or the like, either alone or as a mixture with feeds for pet animals.

[0020] The amount of intake of the prescription diet composition of the present invention per animal per day is preferably 0.1g - 2.5g for pet animals having a body weight of less than 5 kg, 0.2g - 5.0g for pet animals having a body weight of 5 kg or between 5 and 10 kg, 0.3g - 7.5g for pet animals having a body weight of 10 kg or between 10 and 15 kg, and 0.5g - 20g for pet animals having a body weight of 15 kg or above. The number of intake times is not particularly restricted, so long as the desired effect is manifested, but the daily intake amounts are preferably divided into two or more aliquots.

[0021] Examples of daily intake amounts of the prescription diet composition of the present invention are given below.

Pet animals having a body weight of less than 5 kg

[0022]

$\gamma$ -linolenic acid	4 - 250 mg
Biotin	0.05 - 10 mg
Bifid bacteria	0.1 $\mu$ g ~ 100 mg as dry cell weight ( $10^6$ - $10^{10}$ cells per gram of the composition)

EP 0 609 056 B1

Pet animals having a body weight of 5 kg or between 5 and 10 kg

[0023]

- 5     $\gamma$ -linolenic acid    8 - 500 mg  
     Biotin            0.1 - 20 mg  
     Bifid bacteria    0.1  $\mu$ g ~ 100 mg as dry cell weight ( $10^6$  -  $10^{10}$  cells per gram of the composition)

Pet animals having a body weight of 10 kg or between 10 and 15 kg

10

[0024]

- $\gamma$ -linolenic acid    12 - 750 mg  
     Biotin            0.15 - 26 mg  
15    Bifid bacteria    0.1  $\mu$ g ~ 100 mg as dry cell weight ( $10^6$  -  $10^{10}$  cells per gram of the composition)

Pet animals having a body weight of 15 kg or above

[0025]

20

- $\gamma$ -linolenic acid    20 - 2,000 mg  
     Biotin            0.25 - 32 mg  
     Bifid bacteria    0.1  $\mu$ g ~ 100 mg as dry cell weight  $10^6$  -  $10^{10}$  cells per gram of the composition)

- 25    [0026] Prophylactic and therapeutic effects against pet dermatosis are produced by having pet animals ingest the prescription diet composition of the present invention.

- [0027] The mechanism of the prophylactic and therapeutic effect is not completely clarified. It is considered that since the intestinal bacterial flora is improved by the antifatulent, and since the orally ingested poly-unsaturated fatty acid and/or biotin are less decomposed and less assimilated in the intestine and more effectively absorbed in the intestine, improvement in metabolism of fatty acids produces prophylactic and therapeutic effect against dermatosis, etc.

- 30    [0028] The present invention is described in the following Examples, Reference Examples and Experimental Examples.

Example 1

35

- [0029] A 420g portion of flaky "Linax" (product of Idemitsu Petrochemical Co.: dried cells of Mucor bacteria containing 10%  $\gamma$ -linolenic acid; and the same product was used in the Examples hereinafter) was finely divided in a mortar to less than 100 mesh. To the resulting granules were added 80g of "Rovimix H-2" (product of Nihon Roche Co.; biotin content 2%; and the same product was used in the Examples hereinafter) which had been passed through a 100 mesh sieve and 500g of "Korolac D" (product of Nisshin Flour Milling Co.; containing 109 cells or more of Bifidobacterium pseudo-  
40    longum SS-24 strain per 1 gram of the product; and the same product was used in the Examples hereinafter), and the mixture was thoroughly mixed with a rocking mixer to obtain the prescription diet composition of the present invention.

Example 2

45

- [0030] An 80g portion of "Rovimix H-2" which had been passed through a 100 mesh sieve, 500g of "Korolac D" and 420g of lactose (product of Megure Co.; the same product was used in the Examples hereinafter) were adequately mixed together with a rocking mixer to obtain the prescription diet composition of the present invention.

50    Example 3

- [0031] The prescription diet composition was prepared by the same method as described in Example 1, except that 420g of  $\alpha$ -linolenic acid powder (cyclodextrin clathrate powder containing 20%  $\alpha$ -linolenic acid) produced according to the method described in Japanese Published Unexamined Patent Application No. 41395/84 was used instead of  
55    "Linax".

Example 4

5 [0032] The prescription diet composition was prepared by the same method as described in Example 1, except that 420g of DHA powder (cyclodextrin clathrate powder containing 14% DHA) produced according to the method described in Japanese Published Unexamined Patent Application No. 41395/84 was used instead of "Linux".

Example 5

10 [0033] The prescription diet composition was prepared by the same method as described in Example 1, except that 500g of "Biofermin for animals" (product of Biofermin Seiyaku Co.;  $10^9$  cells of *Streptococcus fecalis* and  $10^9$  cells of *Lactobacillus acidophilus* per 10g) was used instead of "Korolac D".

Example 6

15 [0034] The prescription diet composition was prepared by the same method as described in Example 1, except that 500g of "Miyari cell powder for incorporation" (product of Miyarisan Co.; containing 30 mg of *Clostridium butyricum* per 1 gram of the product) was used instead of "Korolac D".

Reference Example 1

20 [0035] A 420g portion of flaky "Linux" was finely divided in a mortar to less than 100 mesh. To the resulting granules were added 80g of "Rovimix H-2" which had been passed through a 100 mesh sieve and 500g of lactose and the mixture was thoroughly mixed with a rocking mixer to obtain a composition.

25 Reference Example 2

[0036] An 80g portion of "Rovimix H-2" which had been passed through a 100 mesh sieve and 920g of lactose were adequately mixed with a rocking mixer, to obtain a composition.

30 Reference Example 3

[0037] A 0.8g portion of "Rovimix H-2" which had been passed through a 100 mesh sieve and 999.2g of lactose were adequately mixed with a rocking mixer, to obtain a composition.

35 Reference Example 4

[0038] A 500g portion of "Korolac D" which had been passed through a 100 mesh sieve and 500g of lactose were adequately mixed with a rocking mixer, to obtain a composition.

40 Experimental Example 1 Prophylactic effect in dogs

[0039] Eighteen household-bred dogs having a body weight of  $5.0 \pm 1.0$  kg and with a history of dermatosis were arbitrarily selected and divided into 3 groups, A, B and C, each consisting of 6 dogs. Dog food was mixed with the following three types of the composition so as to provide a daily intake of 0.1g per 1 kg of body weight; the composition obtained in Example 1 for group A, the composition obtained in Reference Example 1 for group B, and lactose alone for group C. The dogs were fed three times a day. Each of the components in 1 gram of the composition given to each group is identified in Table 1.

45 [0040] The above experiment was conducted over a 2 month period, during which the condition of the skin was observed on the basis of the evidence of itching, redness, eczema, alopecia and crusts. The results are shown in Table 2.

Table 1

Each component in 1 gram of the composition given to each group (mg)			
	Group A	Group B	Group C
$\gamma$ -linolenic acid	42	42	0
Biotin	1.6	1.6	0
Korolac D	500	0	0
Lactose	0	500	1000

Table 2

Number of dogs suffering from dermatosis			
	Group A	Group B	Group C
Number of dogs	1	4	6

[0041] As shown in Table 2, dermatosis can be prevented by feeding the dog food containing the composition of the present invention to dogs.

#### Experimental Example 2 Prophylactic effect in dogs

[0042] Six household-bred dogs having a body weight of  $5.0 \pm 1.0$  kg and with a history of dermatosis were arbitrarily selected. Separately from dog food, the composition obtained in Example 1 was ingested once a day, in an amount of 0.1g per 1 kg of body weight.

[0043] The experiment was conducted over a 2 month period, during which the condition of the skin was observed on the basis of the evidence of itching, redness, eczema, alopecia and crusts. It was observed that dermatosis occurred in only 2 dogs.

#### Experimental Example 3 Prophylactic effect in cats

[0044] Eighteen household-bred cats having a body weight of  $3.5 \pm 1.0$  kg and with a history of dermatosis were arbitrarily selected and divided into 3 groups, A, B and C, each consisting of 6 cats. Cat food was mixed with the following three types of the composition so as to provide a daily intake of 0.1g per 1 kg of body weight; the composition obtained in Example 1 for group A, the composition obtained in Reference Example 1 for group B, and lactose alone for group C. The cats were fed three times a day. Each of the components in 1 gram of the composition given to each group was the same as in Table 1.

[0045] The above experiment was conducted over a 2 month period, during which the condition of the skin was observed on the basis of the evidence of itching, redness, eczema, alopecia and crusts. The results are shown in Table 3.

Table 3

Number of cats suffering from dermatosis			
	Group A	Group B	Group C
Number of cats	0	4	6

[0046] As shown in Table 3, dermatosis can be prevented by feeding the cat food containing the composition of the present invention to cats.

# EP 0 609 056 B1

## Experimental Example 4 Prophylactic effect in cats

[0047] Six household-bred cats having a body weight of  $3.5 \pm 1.0$  kg and with a history of dermatosis were arbitrarily selected. Separately from cat food, the composition obtained in Example 1 was ingested once a day, in an amount of 0.1g per 1 kg of body weight.

[0048] The experiment was conducted over a 2 month period, during which the condition of the skin was observed on the basis of the evidence of itching, redness, eczema, alopecia and crusts. It was observed that dermatosis occurred in only 1 cat.

## Experimental Example 5

[0049] Therapeutic effect in cats (effect when used in combination with an antipruritic agent)

[0050] Fifteen cats having a body weight of  $3.5 \pm 1.0$  kg and suffering from eczema such as redness, etc. were divided into 5 groups, A, B, C, D and E, each consisting of 3 cats. Separately from cat food, the following three types of the composition were ingested once a day over a period of 10 days, in an amount of 0.3g per 1 kg of body weight, the composition obtained in Example 1 to groups A and D, the composition obtained in Reference Example 1 to group B, and lactose alone to groups C and E. The condition of the skin was observed. Prednisolone ("Prednisolone injection", product of Fujita Seiyaku Co.), which was a dermatotherapeutic medicine was subcutaneously injected once a day to groups D and E in an amount of 0.4 mg/kg body weight. Each of the components in 1 gram of the composition given to each group is shown in Table 4.

Table 4

Each component in 1 gram of the composition (mg)					
	Group A	Group B	Group C	Group D*	Group E*
$\gamma$ -linolenic acid	42	42	0	42	0
Biotin	1.6	1.6	0	1.6	0
Korolac D	500	0	0	500	0
Lactose	0	500	1000	0	1000
Note: The "*" denotes the groups having simultaneous administration of prednisolone.					

[0051] The symptoms on the 3rd, 7th and 10th day from the initial administration of composition with or without prednisolone were determined for each cat on the basis of the score shown in Table 5. The average scores were obtained for each group, and shown in Table 6.

Table 5

Score for determination of skin symptoms	
Skin symptoms	Scale
Completely cured	3
Considerably cured	2
Somewhat cured	1
Remained unchanged	0
Somewhat worse	-1
Considerably worse	-2
Extremely worse	-3

Table 6

Determination of skin symptoms					
	Group A	Group B	Group C	Group D	Group E
3rd day	0.3	0	-1.3	1.0	0.7
7th day	1.0	0.7	-3.0	3.0	1.7
10th day	2.0	0.7	NT	NT	2.0

Note: NT: not tested  
 (1) The skin symptoms in three cats of Group C got worse on the 7th day from the initial administration, and therefore the test was suspended.  
 (2) The skin in all 3 cats of Group D was completely recovered on the 7th day from the initial administration, and therefore the test was suspended.

[0052] As shown in Table 6, dermatosis is treated by having cats ingest the prescription diet composition of the present invention, and the therapeutic effect is enhanced when it is used in combination with a dermatotherapeutic medicine. It is possible to reduce the dosage of the dermatotherapeutic medicine, and thus to minimize the occurrence of side effects due to the dermatotherapeutic medicine.

#### Experimental Example 6 Therapeutic effect in dogs

[0053] Ten dogs having a body weight of  $10.0 \pm 1.0$  kg and suffering from slight eczema such as redness, etc. were divided into 5 Groups, A, B, C, D and E, each consisting of 2 dogs. Separately from dog food, the five types of the composition were ingested once a day over a period of 14 days, in an amount of 0.25g per 1 kg of body weight: the composition obtained in Example 2 to Group A, the compositions obtained in Reference Examples 2, 3 and 4 to Groups B, C and D, respectively, and lactose alone to Group E: The condition of the skin was observed. Each of the components in 1 gram of the composition given to each group is shown in Table 7.

Table 7

Each component in 1 gram of the composition (mg)					
	Group A	Group B	Group C	Group D	Group E
Biotin	1.6	1.6	0.016	0	0
Korolac D	500	0	0	500	0
Lactose	420	920	999.2	500	1000

[0054] The symptoms on the 3rd, 7th and 14th day were determined for each dog on the basis of the score shown in Table 5. The average scores were obtained for each group, and shown in Table 8.

Table 8

Determination of skin symptoms					
	Group A	Group B	Group C	Group D	Group E
3rd day	0.5	0	-1.0	-0.5	-1.0
7th day	1.0	0.5	-2.5	-1.5	-2.5



EP 0 609 056 B1

Table 8 (continued)

Determination of skin symptoms					
	Group A	Group B	Group C	Group D	Group E
14th day	1.5	0.5	NT	NT	NT
Note: (1) NT: not tested The skin symptoms in the dogs of Groups C, D and E got worse on the 7th day from the initial intake, and therefore the test was suspended.					

[0055] As shown in Table 8, the composition of the present invention exhibited a more notable therapeutic effect against dermatosis than the compositions containing biotin or bifidobacteria alone.

Experimental Example 7 Therapeutic effect in dogs

[0056] To a Shih Tzu dog (3 years old, female, body weight 5.5 kg) suffering with eczema and pruritus in the tail head and pubic regions due to flea parasites, 1.25 mg of prednisolone was orally administered twice a day over a period of 5 days, separately from dog food. The skin symptoms were not alleviated, and deposition of a light pigment was also observed in the pubic region.

[0057] The dog was subjected to once-a-day intake of 0.55g of the composition obtained in Example 1, while orally administering 1.25 mg of prednisolone twice a day. The pruritus, eczema and pigment disappeared on the 3rd day from the initial intake of the composition.

Experimental Example 8 Therapeutic effect in dogs

[0058] To an Akita-dog (3 years old, male, body weight 33.0 kg) emitting a foul odor due to inflammation and purulence of the external auditory canal of the left ear, four tablets of Jumihaijo (product of Shinwa Seiyaku Co.) was orally administered once a day, and also 6.6g of the composition obtained in Example 1 was ingested once a day, separately from dog food. The diseased part was dried and healed on the 3rd day from the initial intake of the composition.

Experimental Example 9 Therapeutic effect in cats

[0059] To a Japanese cat (10 years old, male, body weight 4.7 kg) suffering with crusts, pruritus, inflammation, alopecia on the left hind leg, and eczema of the dorsum, 4.7 mg of prednisolone and 118 mg of chloromycetin were subcutaneously injected once a day and also 1.4g of the composition obtained in Example 1 was ingested once a day, separately from cat food. On the 7th day from the initial intake, the dorsal eczema was still slightly observed, and the pruritus and inflammation had disappeared.

Experimental Example 10 Therapeutic effect of the  $\alpha$ -linolenic acid-containing composition in dogs

[0060] By a Shih Tzu dog (3 years old, male, body weight 4.9 kg) suffering with slight eczema including redness in the tail head region, 0.5g of the composition obtained in Example 3 was ingested twice a day, separately from dog food. On the 10th day from the initial intake, the diseased part healed.

Experimental Example 11 Therapeutic effect of the DHA-containing composition in cats

[0061] By a Japanese cat (9 years old, female, body weight 4.9 kg) suffering with slight eczema including redness in the dorsal region, 0.5g of the composition obtained in Example 4 was ingested twice a day, separately from cat food. On the 10th day from the initial intake of the composition, the diseased part healed.

Experimental Example 12 Therapeutic effect of the lactic acid bacteria containing composition in dog

[0062] A Shih Tzu dog (4 years old, male, body weight 6.0 kg) suffering from slight eczema including redness in the tail head region, ingested twice a day 0.5g of the composition obtained in Example 5, separately from dog food. On the 7th day from the initial intake of the composition, the diseased part healed.

## EP 0 609 056 B1

### Experimental Example 13 Therapeutic effect of the butyric acid bacteria containing composition in dogs

[0063] A Shih Tzu dog (3 years old, male, body weight 5.5 kg) suffering with slight eczema including redness in the tail head region ingested twice a day 0.5g of the composition obtained in Example 6, separately from dog food. On the 7th day from the initial intake of the composition, the diseased part healed.

### Claims

1. A composition for use as a diet composition for a pet animal, which comprises an antifatulent; a poly-unsaturated fatty acid selected from the group consisting of  $\gamma$ -linolenic acid,  $\alpha$ -linolenic acid, eicosapentaenoic acid and docosahexaenoic acid; and biotin.
2. A composition according to claim 1, wherein the antifatulent is cells of a bacterium.
3. A composition according to claim 2, wherein the bacterium is selected from lactic acid bacterium, bifid bacterium, butyric acid bacterium and bacillus.
4. A composition according to any preceding claim, wherein biotin is contained in a proportion of 0.01 - 1.0 wt%.
5. A composition according to any preceding claim, wherein the poly-unsaturated fatty acid selected from the group consisting of  $\gamma$ -linolenic acid,  $\alpha$ -linolenic acid, eicosapentaenoic acid and docosahexaenoic acid is contained in a proportion of 0.5 - 50 wt%.
6. A composition according to any preceding claim, wherein the antifatulent is contained in a proportion of 0.00001 - 10% wt%.
7. A composition according to any one of claims 1 to 5 wherein the antifatulent is contained in a concentration of  $10^6$  -  $10^{10}$  cells per gram of the composition.
8. A composition according to any preceding claim which comprises  $\gamma$ -linolenic acid, an antifatulent and biotin.
9. Use of a composition of any preceding claims for the preparation of a medicament for the treatment of dermatosis in a pet animal.
10. Use of a composition according to claim 9, wherein the pet animal is a dog or cat.

### Patentansprüche

1. Zusammensetzung zur Verwendung als diätetische Zusammensetzung für ein Haustier, umfassend ein Antiflatulenzmittel, eine mehrfach ungesättigte Fettsäure, ausgewählt aus  $\gamma$ -Linolensäure,  $\alpha$ -Linolensäure, Eicosapentaensäure und Docosahexaensäure, und Biotin.
2. Zusammensetzung nach Anspruch 1, wobei als Antiflatulenzmittel Bakterienzellen dienen.
3. Zusammensetzung nach Anspruch 2, wobei das Bakterium ausgewählt ist aus einem Milchsäurebakterium, einem Bifidobakterium, einem Buttersäurebakterium und Bacillus.
4. Zusammensetzung nach einem der vorangehenden Ansprüche, wobei Biotin in einem Anteil von 0,01 bis 1,0 Gew.-% enthalten ist.
5. Zusammensetzung nach einem der vorangehenden Ansprüche, wobei die aus  $\gamma$ -Linolensäure,  $\alpha$ -Linolensäure, Eicosapentaensäure und Docosahexaensäure ausgewählte mehrfach ungesättigte Fettsäure in einem Anteil von 0,5 bis 50 Gew.-% enthalten ist.
6. Zusammensetzung nach einem der vorangehenden Ansprüche, wobei das Antiflatulenzmittel in einem Anteil von 0,00001 bis 10 Gew.-% enthalten ist.
7. Zusammensetzung nach einem der Ansprüche 1 bis 5, wobei das Antiflatulenzmittel in einer Konzentration von  $10^6$

**EP 0 609 056 B1**

bis  $10^{10}$  Zellen pro Gramm der Zusammensetzung enthalten ist.

8. Zusammensetzung nach einem der vorangehenden Ansprüche, umfassend  $\gamma$ -Linolensäure, ein Antiflatulenzmittel und Biotin.

9. Verwendung einer Zusammensetzung nach einem der vorangehenden Ansprüche für die Herstellung eines Medikaments zur Behandlung von Dermatosen in einem Haustier.

10. Verwendung einer Zusammensetzung nach Anspruch 9, wobei das Haustier ein Hund oder eine Katze ist.

**Revendications**

1. Composition destinée à être employée comme additif alimentaire pour animaux de compagnie, laquelle composition contient un antiflatulent, de la biotine et un acide gras polyinsaturé choisi dans l'ensemble que constituent l'acide  $\gamma$ -linoléique, l'acide  $\alpha$ -linoléique, l'acide eicosapentaénoïque et l'acide docosahexaénoïque.

2. Composition conforme à la revendication 1, dans laquelle l'antiflatulent est constitué de cellules de bactéries.

3. Composition conforme à la revendication 2, dans laquelle les bactéries sont choisies parmi des bactéries lactiques, des bactéries bifides, des bactéries butyriques et des bacilles.

4. Composition conforme à l'une des revendications précédentes, qui contient de la biotine à raison de 0,01 à 1,0 % en poids.

5. Composition conforme à l'une des revendications précédentes, qui contient ledit acide gras polyinsaturé, choisi dans l'ensemble que constituent l'acide  $\gamma$ -linoléique, l'acide  $\alpha$ -linoléique, l'acide eicosapentaénoïque et l'acide docosahexaénoïque, à raison de 0,5 à 50 % en poids.

6. Composition conforme à l'une des revendications précédentes, qui contient ledit antiflatulent à raison de 0,00001 à 10 % en poids.

7. Composition conforme à l'une des revendications 1 à 5, qui contient ledit antiflatulent en une concentration de  $10^6$  à  $10^{10}$  cellules par gramme de composition.

8. Composition conforme à l'une des revendications précédentes, qui contient de l'acide  $\gamma$ -linoléique, un antiflatulent et de la biotine.

9. Emploi d'une composition conforme à l'une des revendications précédentes pour la préparation d'un médicament destiné au traitement d'une dermatose chez un animal de compagnie.

10. Emploi d'une composition, conforme à la revendication 9, ledit animal de compagnie étant un chien ou un chat.